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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/642,946	08/18/2003	James W. Ryan	JR-14000-CON	4300

7590 08/07/2006
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P.O. Box 806
Pelham, NY 10803

EXAMINER

ZARA, JANE J

ART UNIT	PAPER NUMBER
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1635

DATE MAILED: 08/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/642,946

Applicant(s)

RYAN, JAMES W.

Examiner

Jane Zara

Art Unit

1635

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 May 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4, 6-16 and 23-26 is/are pending in the application.
- 4a) Of the above claim(s) 7, 9, 12, 13 and 23-26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-4, 6, 8, 10, 11 and 14-16 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

This Office action is in response to the communication filed 5-21-06.

Claims 1-4, 6-16, 23-26 are pending in the instant application.

Election/Restriction

Applicant's election with traverse of Group I, claims 1-4, 6, 8, 10, 11 and 14-16, and SEQ ID No. 6, in the reply filed on 5-21-06 is acknowledged. The traversal is on the ground(s) that all of the Groups are related and ultimately linked and the search of all of the inventions would not pose a serious burden on the Examiner. Applicant also argues that ten sequences normally constitute a reasonable number of sequences for examination purposes, according to the MPEP at 803.04.

This is not found persuasive because the various inventions claimed encompass different and distinct methods as well as chemically, functionally and biologically different and distinct compositions. The searches required for proper examination of all of the inventions claimed would pose a serious search burden on both the Examiner as well as the facilities of the PTO, since all of the searches required would not be coextensive with each other (e.g. of the different sequences claimed, of the different methods claimed), although some of the required searches may overlap in part. Furthermore, the MPEP citation mentioned by Applicant provides a suggested (as opposed to required) number of sequences considered reasonable to search. The suggested guidelines were written at a time when the data bases contained far less data than now, and so a search of up to ten sequences was less burdensome in the past. For these reasons, the restriction requirement mailed 4-21-06 was proper.

The requirement is still deemed proper and is therefore made FINAL.

Claims 7, 9, 12, 13, 23-26 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 5-21-06.

In light of the amendments filed 5-21-06, an examiner's action on the merits of the amendments and arguments filed by applicant on 5-21-06 insofar as they pertain to the elected invention is hereby deferred until an election has been made. (See MPEP 810.02 and 811).

Pursuant to 35 U.S.C. 121 and 37 C.F.R. 1.141, the different target introns listed in claim 8, and encompassed in claims 11, 14-16, are subject to restriction. As per M.P.E.P. 2434, "the Commissioner has partially waived the requirements of 37 C.F.R. 1.141 and will permit a reasonable number of such nucleotide or amino acid sequences to be claimed in a single application." Applicant is required to elect a single intron region sequence from claim 8 (see also e.g. Table 2, pages 72-73 of the specification). Those sequences which are patentably indistinct from the sequence selected by the Applicant will also be examined.

Claim 8 specifically claims different nucleic acid sequence targets (*i.e.* different introns). Each of these target sequences is considered to be structurally independent, because each of these sequences has a unique nucleotide sequence. Furthermore, a search of all the sequences or targets claimed presents an undue burden on the Patent

and Trademark Office to search and examine all of the recited or encompassed sequences. In view of the foregoing, applicants are required to elect up to ONE (1) claimed target intronic sequence.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

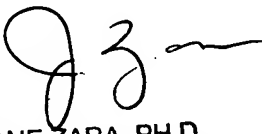
Certain papers related to this application may be submitted to Art Unit 1635 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. ' 1.6(d)). The official fax telephone number for the Group is **571-273-8300**. NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO

DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Jane Zara** whose telephone number is **(571) 272-0765**. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras, can be reached on (571) 272-4517. Any inquiry regarding this application should be directed to the patent analyst, Katrina Turner, whose telephone number is (571) 272-0564. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jane Zara
8-3-06

 TC 1600
JANE ZARA, PH.D.
PRIMARY EXAMINER